

APR - 7 1997 K970157

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
LASERSCOPE AUTOMATIC EYE PROTECTION FILTER**

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**REGULATORY AUTHORITY:**

Safe Medical Devices Act of 1990, 21 CFR 807.92

**COMPANY NAME/CONTACT:**

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Laserscope  
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**DEVICE TRADE NAME:**

Laserscope Automatic Eye Protection Filter

**DEVICE COMMON NAME:**

Automatic Eye Protection Filter

**DEVICE DESCRIPTION:**

The Laserscope Automatic Eye Protection Filter (AEPF) is a mechanical shutter that moves protective filter(s) into the line of view before the laser beam is emitted from the laser aperture. The AEPF is automatically activated when the laser foot pedal is pressed. The AEPF provides the user with an unobstructed view of the target when the laser is not activated. The AEPF is connected to the laser by an electrical cable which interfaces with the main control board. The drive/control electronics are monitored by the laser system's microprocessor. The software default is to ask the user if they want to disable the Automatic Eye Protection Filter. In order to activate the laser beam, the user must attach the Automatic Eye Protection Filter or disable the feature through the laser's control panel if they do not plan to utilize the device.

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**DEVICE CLASSIFICATION:**

To the best of our knowledge, Automatic Eye Protection Filters have not been specifically classified; however, the surgical lasers for which they are intended have been classified as Class II medical devices by the OB/GYN, General Plastic Surgery, and ENT Device Advisory Panels.

**PERFORMANCE STANDARDS:**

The Laserscope Orion and Aura Surgical Laser Systems conform with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems. Laserscope is unaware of any specific standards for Automatic Eye Protection Filters.

**INDICATION FOR USE STATEMENT:**

The Laserscope Automatic Eye Protection Filter is intended to be used in conjunction with an endoscope or microscope for all cleared Laserscope indications for the Orion and Aura Surgical Laser Systems.

**COMPARISON WITH PREDICATE DEVICE:**

The Laserscope Automatic Eye Protection Filter is substantially equivalent (identical) to the Automatic Eye Protection Filter which is an integral part of the Laserscope 800 Series Surgical Laser System.

The risks and benefits for the Laserscope Automatic Eye Protection Filter are comparable to the predicate device when used for similar clinical applications.

Since the Laserscope Automatic Eye Protection Filter is substantially equivalent with respect to indications for use, materials, method of operation and physical construction to the predicate device, we believe it clearly meets the requirements for substantial equivalence according to Section 510(k) guidelines. Safety and effectiveness are reasonably assured, therefore justifying 510(k) clearance for commercial sale.

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